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Food and Drug Administration College Park, MD 20740

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MAR 8 2004

Mr. Petra Augenstein-Caporale Chief Pharmacist Waleda, Inc. 175 North Route 9W Congers, New York 10920

Dear Mr. Augenstein-Caporale:

This is in response to your letter of February 5, 2004 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your letter for the product "Nursing Tea" included the product label, which does not comply with the labeling requirements for dietary supplements in 21 CFR 101.36.

The product, which is labeled as a dietary supplement, bears a "Nutrition Facts" panel when in fact it is required to bear a "Supplement Facts" label in accordance with 21 CFR 101.36. A dietary supplement that does not bear nutrition labeling in accordance with 21 CFR 101.36 is misbranded under section 403(q)(5)(F) of the Act.

The label also states that it is "Certified Organic Herb Tea." The use of the term "organic" in labeling of foods is governed by the requirements of the Organic Foods Production Act (OFPA), enacted under Title 21 of the 1990 Farm Bill. Under this authority, the U.S. Department of Agriculture established uniform national standards for the production and handling of foods labeled as "organic." The Act authorized a new USDA National Organic Program (NOP) to set national standards for the production, handling, and processing of organically grown agricultural products. In addition, the Program oversees mandatory certification of organic production. The Act also established the National Organic Standards Board (NOSB) which advised the Secretary of Agriculture in setting the standards upon which the NOP is based. Producers who meet standards set by the NOP may label their products as "USDA Certified Organic." You can find more information on whether your product is eligible to be labeled using the term "organic" at the NOP web site (see

http://www.nalusda.gov/afsic/AFSIC_pubs/orgusda.htm and http://www.nalusda.gov/afsic/ofp/ofp.htm.

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Please contact us if we may be of further assistance.

Sincerely yours,

Susan J. Walker, M.D.

Director

Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300 FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, New York District Office, Office of Compliance, HFR-NE140



Office of Nutritional Products
Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Pkwy
COLLEGE PARK
MD 20740

FER 8 2004

February 5, 2004

Re: NURSING TEA

Pursuant to 21 CFR Part 101.93, Weleda, Inc. is filing a Statement of Nutritional Support for the Dietary Supplement marketed as NURSING TEA. Please note that the formula has been changed as stated below; the product with the previous formulation is not marketed any more.

- 1. Marketed by: Weleda, Inc., 175 North Route 9W, Congers, NY 10920.
- 2. Text of Nutritional Support Statement being made: "Supports Healthy Lactation."
- 3. Name of dietary ingredients: Fenugreek seed, Anise seed, Fennel seed, Caraway seed and Lemon verbena leaves.
- Brand Name: NURSING TEA.
- 5. Substantiation information on file at the company office. The corporate officer who can certify same is Erk Schuchhardt, President of Weleda, Inc.

A copy of the labeling is attached (box).

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Yours truly.

Petra Augenstein-Caporale, RPh

Chief Pharmacist

Weleda, Inc.

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Weleda, Inc., 175 North Route 9W, Congers, NY 10920

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Dietary supplement Supports Healthy Lactation*



Herb Tea

Mode d'emploi : Placer un sachet de tisane dans une tasse d'eau bouillante. Couvrir et laisser infuser pendant 5 minutes. Boire jusqu'à 3 tasses par jour. Etant donné qu'il est essentiel d'utiliser de l'eau de qualité pour obtenir une bonne tisane, nous recommandons de l'eau de source ou de l'eau fittrée afin d'optimiser les résultats. Ingrédients : Fenugnec (graines), nous (graines), fenouait (graines), carvi (graines), verveine citronnelle (feuilles). Tous les ingrédients qui composant notre tisane d'allaitement sont cutivés et récoltès selon les normes de qualité de WELEDA, et sont certifiés biologiques par BCS OKO-GARANTIE GMBH, Allemagne. Aucun arbne, agent conservateur ou éduicorant n'a été ajouté à ce produit. Précautions : Ne pas utiliser si vous êtes allergique à l'aris, à l'anéthole ou à tout autre ingrécient contenu dans cette infusion. Si vous souffrez d'allergie au céleri ou êtes sous traitement contre le diabète, veuillez consulter un professionnel de la santé avant d'utiliser ce produit. Les personnes atteintes de maladies du rein ou du cœur doivent utiliser ce produit avec précaution. Si une éruption outanée survient, cesser l'emploi et consulter un médecin. Grossesse: Ce produit est recommandé pour les fernmes qui aliaitent. Il ne devrait pas être utilisé durant une grossesse sans avoir consulté un médecin traitant.

*Cette allégation n'a pas été évaluée par la FDA. Ce produit n'est pas destiné à diagnostiquer, traiter, guérir ou prévenir des maladies.



Nursing Tea

Dietary supplement Supports Healthy Lactation*



20 TEA BAGS 14 OZ (40g)

Apply this essential balsam for the care of cuts, skin abrasions and slow-healing wounds. Active ingredients: Mercurialis perennis Tincture (M), Calendula officinalis Tincture (M).

Arnica Ointment
Use WELEDA's Amica Ointment for bruses, sprains, sore and aching
muscles, black and blue marks. Active ingredient: Amica montana
Tincture (N).

A soothing, cooling gel, WELEDA's Burn-Care offers treatment of minor household's burns, sunburns and insect bites. Active ingredients: Urtica urens 1X, Arnica montana 1X.

venaouron usg romer Revitalizes and tones tired legs. With copper and various plant extracts, this gel helps ease the feeling of discomfort and heaviness in tired feet and legs. Useful during pregnancy, as well as for people who are on their feet a lot.

Foot Balm Vvelede's Foot Balm contains myrth and calendula in a citrus base; it cook, softens calluses and revitalizes the skin. It does not contain menthol, which could be imitating.

convenient poliet form, used for the temporary relief of sleeplessnes nervousness and agitation. Active ingredients: Avera sativa Tircture (M), Valeriana Tircture (N), Passiflora incamata Tircture (N), Coffee tosta Decoction, Humulus lupulus Tircture (N).

Apply this essential balsam for the care of cuts, skin abrasions and slow-healing wounds. Active ingredients: Mercurialis perennis Tincture (M), Calendula officinalis Tincture (M).

WELEDA NURSING TEA - Certified organic, rich in vitamins and minerals

Mother's Milk is a complete and perfect nourishment. Generally, breast-fed babies develop harmoniously, partly due to the dose bond formed between mother and child. Breast-feeding provides a basis for good health throughout life. Even the best substitutes cannot impart the resistance to illnesses that mother's milk provides.

> digestible and rich in vitamins and minerals. WELEDA's thy lactation*, but it also has a soothing effect on the 'A's Nursing Tea has been sold to thousands of satisfied

v.weieda.com or call (800) 241-1030

he FDA. This product is not intended to diagnose,

Directions: Add one tea bag to a cup of boiling water. Cover and let stand for 5 minutes. Drink up to 3 cups daily, Because good water is essential to brewing a great cup of tea, we recommend using spring or filtered water to ensure the best result.

Ingredients: Fenugreek seed, Anise seed, Fennel seed, Caraway seed and I enron water to the seed.

and Lethion Verbies leaves.
All the ingredients in our Nursing Tea are grown and harvested according to WELEDA quality standards and are certified organic by BCS OKO-GARANTIE GMBH Germany.
No flavorings, preservatives or sweeteners are added to this product.

BCS OKO-GARANTIE GMBH Termany.

No flavorings, preservatives or sweeteners are added to this product. Warnings: Do not use if you are allergic to anise, anethole, or any of the ingredients of this tea. If you have a celery allergy or are being treated for diabetes, corsult a health professional before use. Use with caution in individuals with kidney and heart disease. If you experience a skin rash, discontinue use and consult your doctor. This product is intended for lactating women, and should not be used during pregnancy without consulting with your health are assentiales. care provider.

*This statement has not been evaluated by FDA. This product is not intended to diagnose, treat, cure or prevent any disease.

Made in Germany / Fabriqué en Allemagne Distributed by / Distribué par: WELEDA INC., NY – USA / Purity Life Health Products Ltd. Ontario – Canada





Adions and a suffer in measure control A	Protéines 0g	Sucres Og	Total chickles On	Total lipides 0g		Calories: 0 Calories p	Quantité par portion	Portions par bolte : 20	Quantité par portion : 1 sachet (2g)	Valeur nutritive
Shirt of took Choires	moins de 2%		moins de 2%	moins de 2%	% valeur quotidienne**	Calories provenant des matières grasses: 0			vet (2g)	

**Percent values are based on a 2000 calones diet	Protein 0g	Sugars 0g	Total carbohydrates 0g	Sodium 0g	Total fat 0g		Calories. 0	Amount per serving:	Servings per container 20	Serving size, 1 lea Bag (0 0 / oz)
lones diet	less than 2%		less than 2%	less than 2%	less than 2%	%Daily value**	Calories from fat. 0			